K091544

SEP 0 9 2009

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	May 22, 2009	
Device:	Trade Name:	S-Test LD Reagent cartridge
	Classification:	Class II Exempt
	Common/Classification Name:	Lactate Dehydrogenase Test System (21 C.F.R. § 862.1440) Product Code CFJ
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Lactate Dehydrogenase Reagent (k931786)	
Device Description:	The S-Test Lactate Dehydrogenase (LD) reagent cartridge, used with the S40 Clinical Analyzer, is intended for the quantitative *in vitro* diagnostic determination of LD activity in serum based on a photometric test measuring the rate of conversion of NADH from NAD in an enzyme assay. It is composed of a bi-reagent cartridge, and is intended for use in clinical laboratories or physician office laboratories.	
Intended Use:	Indications for use: The S-Test Lactate Dehydrogenase Reagent is intended for the quantitative determination of lactate dehydrogenase activity in serum using the S40 Clinical Analyzer. Lactate Dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.	
Technological Characteristics:	The S-Test LD Reagent is contained in a bi-reagent cartridge. Reagent 1 contains: Lithium L-lactate and diethanolamine buffer. Reagent 2 contains: Nicotinamide adenine dinucleotide.	

Performance Data:	Performance data on the S-Test LD included precision, accuracy, and detection limit data. Precision: In testing conducted at three LD levels for 22 days, the within-run CV ranged from 1.5 to 2.4%, and total CV ranged from 6.4 to 7.1%. In precision studies at three separate Physician Office Laboratory (POL) sites and in-house over 5 days, the within-run CV ranged from 0.9 to 4.3% and total CV ranged from 0.9 to 5.1%. Accuracy: In the correlation study, 81 samples with LD values ranging from 26 to 652 U/L were assayed on the S40 Clinical Analyzer using S-Test LD (y) and a comparative method (x). Least squares regression analysis yielded a correlation coefficient of 0.9857, a standard error estimate of 19.8, a confidence interval slope of 0.934 to 1.008, and a confidence interval intercept of -13.3 to 2.7. In patient correlation studies at four separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients of 0.9971 to 0.9989, standard error estimates of 6.4 to 10.5, confidence interval slopes of 0.941 to 1.001, and a confidence interval intercepts of -11.1 to 11.0. Detection limit: The detection limit was 9 U/L.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Alfa Wassermann, Inc.
c/o Dr. Hyman Katz
4 Henderson Drive
West Caldwell, NJ 07006

SEP 0 9 2009

Re: k091544
Trade/Device Name: S-Test Lactate Dehydrogenase (LD), Model RC 0017
Regulation Number: 21 CFR § 862.1440
Regulation Name: Lactate dehydrogenase test system
Regulatory Class: Class II
Product Code: CFJ
Dated: July 7, 2009
Received: July 8, 2009

Dear Dr. Hyman Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k091544

Device Name: S-Test Lactate Dehydrogenase (LD)

Indication For Use: The S-Test Lactate Dehydrogenase Reagent is intended for the quantitative determination of lactate dehydrogenase activity in serum using the S40 Clinical Analyzer. Lactate Dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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